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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/072,766
Filing Date: February 08, 2002
Appellant(s): SLEPIAN, MARVIN J.

Patrea L. Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/15/08 appealing from the Office action mailed 8/10/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 11/13/07 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,585,716	Altman	7-2003
6,102,887	Altman	8-2000
6,309,370	HAIM	10-2001

Benjamin and McMillan, "Stress (Heat Shock) Proteins Molecular Chaperones in Cardiovascular Biology and Disease" Circ Res, Vol 83 (July 27,1998), pages 117-132.

Brosamle et al "Regeneration of Lesioned Corticospinal Tract Fibers in the Adult Rat Induced by a Recombinant Humanized IN- 1 Antibody Fragment" The Journal of Neuroscience, Vol 20 no.21 (November 1, 2001), pages 8061-8068

Ross, J "Composition of the Heart" online article, (June, 1999), pp 1-5

Williams et al, "The Human Brain: Dissections of the Real Brain, Chapter 1: The Spinal Cord", online article, downloaded September, 2004, pp 1-3.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 4, 6, 7, 15-18, 20-23, 25, 28, 29, 32 and 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,585,716 B2; see entire document). This rejection is set forth in the prior office action mailed 8/10/07 and restated below.

Altman teaches a drug delivery device for methods of treating the heart for injecting therapeutic agents into the myocardium. The method involves penetrating and entering the endomural zone (myocardium) with delivery of the agents to the endomural zone. Agents are delivered in microformulations such as microspheres (encompassing microcapsules and

microparticles) as recited in claim 1. The agents are delivered using a tubular "means for delivery", which is a means of delivery similar to that disclosed in the instant specification. As well, Altman et al teach that controlled release matrices such as those made of polymers can be used to deliver the drug (see e.g. col 6, line 8-13) as recited in claims 3 and together create a bioactive polymer as recited in claim 32. Drugs used include growth factors and peptides and angiogenesis agents (see e.g. col 5, line 48-56 and col 4, line 1) or drugs as recited in claim 3, 6, 7, 28 and 29. The delivery device has a guidance system as recited in claim 23 and a hollow penetrating element i.e. a needle attached to a catheter as recited in claim 36 and 37 (see e.g. bridging paragraph col 3-4). The instant specification teaches that the means for creating a void can be a simple catheter or needle. Therefore, the needle of Altman et al creates a void by insertion and exit from the tissue similar to that recited in claim 15 and 25 and is comprised of metal as recited in claim 16. The catheter is flexible as recited in claim 17. Drugs are stored in a reservoir attached to the catheter and pumped automatically into the lumen of the drug delivery catheter through the penetrating element into the target (see e.g. col 5, line 15-39) as recited in claim 18, 21 and 22. Furthermore, sensors can be used with the device for electrical sensing (see e.g. col 5, line 65-67) as recited in claim 20. The delivery can be percutaneously or surgically (see e.g. col 5 , line 23-28) as recited in claim 35.

Specifically, Altman et al (716) teach, "The catheter distal tip 24 includes a penetrating element 28, for example a curved or helical needle, which is selectively extended from the distal tip and is forced through the wall of the vein, and into the myocardium. Therapeutic agents are then injected into the myocardium through the catheter and needle." And furthermore, "To enhance the retention of the therapeutic agents in the needle track and/or within the myocardium

in the face of natural fluid flow from the myocardium into the vein, the venous flow path is shut off by occluding the coronary ostium 10 with the guide catheter which has occluding mechanism 29". Hence, Altman et al absent evidence to the contrary teaches creation of a void, the needle track which is then filled with agents.

Claims 1, 3, 6, 7, 15-19, 21-23, 25, 34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,102,887; see entire document). This rejection is set forth in the prior office action mailed 8/10/07 and restated below.

Altman teaches a drug delivery device for methods of injecting therapeutic agents into the myocardium through a distensible penetrating element with a chamber for holding the agent (se e.g. abstract). Specifically, the device is designed to penetrate the endocardium and inject drugs deep into the myocardium (see e.g. col 3, line 9-25). Agents are delivered in microformulations such as microspheres or nanoparticles or polymers (see e.g. col 12, line 29-30) as recited in claim 1. The agents are delivered using a tubular "means for delivery", which is a means of delivery disclosed by the instant specification. The agents are in microspheres or nanoparticles, which are locally delivered to the myocardium. Numerous agents are envisioned for delivery such as small molecules and macromolecules such as growth factors and polymers, which would fill the voids (see e.g. col 11 line 1 through 30 and figure 4a) as recited in claims 3, 6, and 7. The device comprises a penetrating end and is a hollow tube such as a needle (see e.g. col 4, line 11-12). Furthermore, an expansile cutter is included with the device. This expansile cutter is comprised of an expanding prong fixation that is sharpened to penetrate and spread the

tissue (see e.g. col 9, line 22-44) as recited in claim 15, 19 and 25. The device comprises a needle and is thus comprised of metal as recited in claim 16. The drug delivery tube is comprised of a catheter and is thus flexible as recited in claim 17, 36 and 37 (see e.g. col 4, line 41-45) and is connected to reservoir (col 3, line 9-25) as recited in claim 18. Osmotic pumps or piston chambers drive drug delivery as recited in claims 21-23 (see e.g. col 6, line 40 through col 7, line 12) and is guided by a guiding catheter (see e.g. col 12, line 61-63) as recited in claim 23. The expansile cutters, create a void into which is deposited the agents for delivery (see e.g. col 10, line 48-54) as recited in claim 34.

Altman et al (887) "The penetrating structure 30 is shown to be a hollow helical needle for securing the delivery catheter to prevent misplacement which may result because of the motion of the beating heart. The drug delivery sites may be in the left ventricular free wall 13, the left ventricular apex 15, or the ventricular septum 18. In other embodiments the penetrating structure could incorporate a solid helix, a hollow centrally located needle, a solid straight centrally located needle, curved needles, engagement pinchers or crossing penetrating needle structures, or appropriate combinations of these structures" (col 4, line 5-14). Inherently the design of the hollow needles leaves needle tracks as explicitly described in Altman (716). Furthermore, Altman (887) teaches use of expanding prong fixation system with prongs. "The prongs are designed to penetrate the body tissue and spread apart when the penetrating drug delivery element (the needles 865) advances axially out the distal end of the catheter body and into the body tissue to be injected" (col 9, lines 33-37). Col 10, line 17 describes the spreading of the prongs, which inherently results in spreading of the tissues, which would create a void.

Claims 1, 3, 6, 7, 14-16, 18, 20-24, 32 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Haim et al, (US 6,309,370 B1; see entire document). This rejection is set forth in the prior office action mailed 8/10/07 and restated below.

Haim et al teach an apparatus for intracardiac administration of growth factors into the myocardium (see e.g. abstract and col 3, line 24-42). Agents are delivered in microcapsules (see e.g. col 7, line 6-16). The agents are delivered using a catheter or tubular "means for delivery", which is a means of delivery disclosed by the instant specification. The drugs are delivered as microcapsules as recited in claim 1. Growth factor drugs such as FGF or VEGF are envisioned for delivery (see e.g. col 9 line 4-10) as recited in claims 3, 6 and 7. The device comprises a laser beam that conveys a wave-guide to create channels into which the drugs are deposited (see e.g. col 5, line 20-21 and col 6, line 41-44) as recited in claims 14 and 34. The drug delivery device comprises a hollow needle, which is inserted into the heart with a laser beam that conveys a wave-guide to create channels or voids (see e.g. col 5, line 20-21 and col 6, line 41-44) as recited in claim 15. The device comprises a needle and is thus comprised of metal as recited in claim 16 and tubular as recited in claim 36. The device is connected to reservoir (col 13, line 1-15) as recited in claim 18 and delivered by pumps and is guided by a guiding catheter (see e.g. col 7, line 25-31) as recited in claims 21-23. A series of sensors for guidance, a position sensor and a optical sensor and one for identification of sites, a physiological sensor, a pressure sensor, an ultrasound sensor (see e.g. col 3, line through col 6, line 28) as recited in claim 20, 24. The organ can be accessed percutaneously (see e.g. col 6, line 30-59) as recited in claim 35.

Haim teaches, "In some of these methods, known commonly as percutaneous myocardial revascularization (PMR), a catheter is inserted into the heart, and a laser beam is conveyed by a waveguide in the catheter to create channels through the endocardium into the myocardium. In others of these methods, known as transmyocardial revascularization (TMR), a probe is inserted through the chest wall and used to create channels that penetrate into a chamber of the heart through the epicardium and the myocardium" (col 6, line 40-46). Similarly to needle tracks, these channels inherently comprise voids or spaces. This is exemplified in col 7, line 6-16), "In these preferred embodiments, the growth factor drug is preferably contained in a slow-release capsule, made of an appropriate solid drug delivery medium, as described, for example, in U.S. Pat. No. 4,588,395 or 4,578,061, mentioned above. The capsule is inserted into the LMR channel or may, alternatively, be forced into the myocardium without the use of LMR."

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim et al, (US 6,309,370 B1; see entire document) in view of Benjamin and McMillan (Circ Res, 1998, Vol 83, pages 117-132; see entire document). This rejection is set forth in the prior office action mailed 8/10/07 and restated below.

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. The device deposits drugs such as heat shock proteins (HSP) into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before except; neither Altman, Altman and Haim et al teach use of heat shock proteins.

Benjamin and McMillan teach that HSP enhances the speed of recovery of the Ischemic Heart (see e.g. page 119, col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drugs and growth factors taught by Altman, Altman and Haim et al with the HSPs taught by Benjamin and McMillan because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to deliver drugs to the myocardium to treat cardiac vascular disease and because Benjamin and McMillan teach that it is within the ordinary skill of the art to enhance recovery of an ischemic heart with administration of hsps. One would have been motivated to do so in order to receive the expected benefit of improved myocardial function, preserved metabolic functional recovery, reduction of infarct size (see e.g. page 119, col 2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brosamle et al (The Journal of Neurosciences, 2000, Vol 20:21, pages 8061-8068; see entire document) in view of Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim et al, (US 6,309,370 B1; see entire document). This rejection is set forth in the prior office action mailed 8/10/07 and restated below.

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. Applicants recite a use of kits comprising devices and a void filling material for nerve regeneration.

Brosamle et al teach the use of a device in which recombinant humanized IN-1 Fad antibody is delivered through by a pump through a catheter to the intrathecal space of the spinal cord. Specifically, a small hole in the dura matter was made and a catheter connected to a small osmotic pump was inserted into the subdural space close to the lesion (see e.g. figure 4). Following administration of rIN-1 Fab induced regeneration of transected spinal cord axons was induced (see e.g. page 8065, col 1, paragraph 3).

Brosamle et al do not teach that the device has an end penetrating or cutting means with which the device is inserted into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the device and methods of treatment for nerve regeneration of Brosamle et al with the device of Altman, Altman and Haim et al because Brosamle et al teach that it is within the ordinary skill of the art to administer drugs through a catheter into the subdural space for infusion into a lesion and because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to use a drug delivery device that delivers drugs into the depths of the tissue. One would have been motivated to do so in order to receive the expected benefit of minimally invasive delivery of drugs in a local sustained manner for more effective drug effects (see e.g. US 6,309,370, col 2, line 50 through col 3, line 11). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

(10) Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 and 103 in the Appeal Brief filed 10/15/08. In general, applicants argue that none of Altman ('716 patent and '887 patent) or Haim et al teach forming a void, cavity or containment space or reservoir are in the endomural zone and furthermore, that each of the references lack complete teachings as presented. Dealing first with Altman ('716), it is argued that '716 teaches insertion of a needle or catheter into the endomural zone, which applicants argue does not create a void. Rather, applicants argue that a needle or catheter must be of a specific bore size to remove tissue, one smaller cannot. However, the instant specification teaches on page 11, beginning in line 21, "How to create repository zones in organ, Voids may be created via simple catheter, trochar or needle insertion. The void may be of identical size to the insertion device. Alternatively, the void may be made larger via expansile cutter systems which fan-out in a radial or conical or other geometric shape way." As this is the extent of the guidance provide in the instant specification on creating the repository, neither the specification nor the claims can be said to provide any distinction between the method of Altman and the instant repository. Secondly, applicants argue that Altman '716 does not teach putting a polymeric material into the void. This argument is traversed as Altman teaches specifically in col 6, line 4-13), "The devices and techniques may be used for delivering drug microformulations such as microspheres and liposomes, and drug delivery structures from an acute use catheter." These microspheres are specifically, "Microsphere structures such as those provided as Alkermes Prolease system are one example of polymeric matrices". Applicants argue that '716 does not teach diagnostic or therapeutic sensors. However, in col 5,

line 65-67 Altman teaches that the device can be combined with permanently implantable devices with and without electrical sensors to provide sustained delivery of therapeutic agents. Applicants argue that '716 does not teach means to transfer particles through the zones or direct guidance. However, injection of the agent requires mechanical acceleration and as well, in col 5, line 15 a guide catheter is taught.

Altman '887 similarly teaches use of a needle, " In other embodiments the penetrating structure could incorporate a solid helix, a hollow centrally located needle, a solid straight centrally located needle, curved needles, engagement pinchers or crossing penetrating needle structures, or appropriate combinations of these structures" (col 4, line 5-14). Furthermore, '887 teaches use of prongs "designed to penetrate the body tissue and spread apart when the penetrating drug delivery element (the needles 865) advances axially out the distal end of the catheter body and into the body tissue to be injected" (col 9, lines 33-37). Col 10, line 17 describes the spreading of the prongs, which inherently results in spreading of the tissues, which would create a void. Based upon guidance in the specification, it is not clear that '887 differs in method from that of the recited claims. Applicants argue that '887 does not teach means to transfer particles through the zones or direct guidance. However, injection of the agent is taught to occur by osmotic pumps and piston chambers which inject the material by mechanical acceleration (col 6, line 40-col 7, line 12) and as well, in col 12, line 61-63 a guide catheter is taught.

Haim et al teach a device that comprises a laser beam that conveys a wave-guide to create channels into which the drugs are deposited (see e.g. col 5, line 20-21 and col 6, line 41-44) and comprises a hollow needle, which is inserted into the heart with a laser beam that conveys a

wave-guide to create channels or voids (see e.g. col 5, line 20-21 and col 6, line 41-44). These very specifically teach formation of voids or channels that are used to be filled with the drug. Furthermore, applicants argue that Haim et al does not teach diagnostic or therapeutic sensors. Applicants argue that '716 does not teach means to transfer particles through the zones or direct guidance As well, in col 5, line 39-42 Haim et al teach use of a piston for transfer into the space. The device comprises a variety of sensors such as pressure sensors, ultrasound sensors and detractor sensors, which can be considered diagnostic and therapeutic sensors (see e.g. col 5-6). Additionally, Haim et al teach position sensors which are used as direct guidance (see e.g. col 4, line 41-43).

Finally, applicants argue that these deficiencies are not cured by the obviousness rejections. As argued above, the primary references provide adequate anticipation of a method of treatment comprising penetrating into an endomural zone of an organ, organ component or tissue structures wherein the method comprises cutting or removing tissue into the zone thus creating a void, cavity or containment area into which is delivered an agent. Hence, the secondary references need not teach what the primary reference teaches.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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